

## **REMARKS**

Entry of this amendment is respectfully requested, as it is believed to place the claims in condition for allowance and would not require further search.

Reconsideration and allowance are respectfully requested.

In this response, claims 1, 6, 9, and 15 are amended for further clarity. Support for the amendments can be found in the specification and claims as originally filed. For example, the specification at page 15, line 5 discloses cell culture in the absence of serum. No new matter is added. Further, claims 17-24 have been withdrawn as being directed to a non-elected invention group. Accordingly, claims 1-6, 8-15, and 17-24 are pending, and claims 1-6 and 8-15 are at issue.

### **Priority**

The Examiner has maintained that the present claims are entitled to a priority date of October 2, 2001, the filing date of US 09/969,357 (the “357 application”). The Examiner has agreed that Danish priority application serial no. DK PA 2000 01456 (the “01456 application”), filed October 2, 2000, discloses large-scale culture in medium lacking serum but not in medium lacking animal-derived components.

To expedite prosecution, the present claims have been amended to require culture in the absence of serum. On this basis, Applicants respectfully request that the Examiner accord the present claims a priority date of October 2, 2000.

### **Information Disclosure Statement**

Applicants again respectfully request clarification of the Examiner’s initial indication that the Information Disclosure Statement filed December 2, 2003 was defective. As previously explained, a Form PTO-1449 was filed on the same date as the Information Disclosure Statement containing all of the references that the Examiner has labeled as being improperly disclosed. Furthermore, PAIR (entry of 8/9/06) indicates that the Examiner considered all of these references and initialed the PTO-1449 form. Applicants merely wish to eliminate any lack of clarity in the file that these references have not been considered.

### **Double Patenting**

Claims 1-6, 8-11, and 15 have been rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-3, 5, 8, 10-13, and 15-17 of commonly assigned application serial no. 10/394,086.

It is believed that this response to the outstanding Office Action will remove all claim rejections other than this double patenting rejection. On that basis, it is respectfully requested that, should the claims be found to be in condition for allowance, the Examiner allow the claims to issue and maintain the double patenting rejections in the remaining application (M.P.E.P. 804).

### **Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claim 10 has been rejected under 35 U.S.C. §112, second paragraph, for indefiniteness, based on a lack of antecedent basis for “the cell-containing carriers”.

In this response, claim 9 has been amended to depend from claim 8, thus, it is believed, providing the requisite antecedent basis. It is believed that this amendment has overcome the rejection.

### **Rejection Under 35 U.S.C. § 112, First Paragraph**

Claims 1-6 and 8-15 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement and lack of written description. The Examiner contends that the term “Factor VIIa” encompasses variants of Factor VII that exhibit equal or improved biological activity and that the specification does not support the full scope of the claims nor indicate that Applicants had possession of the full scope of the claims at the time of filing.

While Applicants disagree with the Examiner’s assertion, in order to expedite prosecution the claims have been amended herein to require that the Factor VII being produced by the claimed method is wild-type Factor VII (which is specifically disclosed at page 6, lines 5-7.) It is respectfully submitted on this basis that this rejection has been overcome.

### **Rejections Under 35 U.S.C. § 103**

Claims 1, 2, 5, 6, 15, and 16 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Ragni, *Haemophilia* 7(supp 1):28-35, 2000; in view of Schmidtchen et al.,

*Am.J.Hum.Genet.* 62:64, 1998. The Examiner contends that Ragni discloses methods for large-scale production of Factor VII in recombinant cells in serum-containing cultures; that Schmidtchen et al. disclose methods for protein production in recombinant CHO cells in the absence of serum; and that it would have been obvious to combine these teachings to achieve the presently claimed invention. This rejection is respectfully traversed.

In view of the amended claims requiring serum-free culture, Applicants believe that the present claims are entitled to the priority of DK PA 2000 01456 and that, consequently, Ragni is not prior art against the present claims (see above).

Furthermore, as discussed in the Amendment filed December 20, 2006, it is apparent from the scientific literature that, prior to the present invention, one of ordinary skill in the art could have had no reasonable expectation of success in practicing the present invention. As pointed out previously, Ragni suggests altering the sequence/structure of the clotting factors (see, e.g., page 32, first column- page 33, second column) as a way to overcome problems of immunogenicity and stability of recombinant proteins, not by optimizing production conditions as in the present invention.

Schmidtchen et al. is silent with regard to large-scale production in serum-free conditions and hence is not directly relevant to the present claims.

Based on the above amendments and remarks, it is believed that the claims are in condition for allowance, and a determination to that effect is earnestly solicited.

Respectfully submitted,

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